

**Patient Group Direction for the supply of Trimethoprim Tablets by Community Pharmacists in the management of Uncomplicated Urinary Tract Infections**

**PGD Development and Clinical Approval**

**PGD Working Group**

This PGD was developed by a working group involving pharmacists from NHS Kernow, GP Clinical leads from NHS Kernow and Microbiology

Name and role	Job title and organisation
<b>Amanda Pell</b> Pharmacist and Lead author	Pharmaceutical Advisor NHS Kernow
<b>Dr Nick Gibson</b> GP	GP Prescribing Lead NHS Kernow Prescribing Lead
<b>Georgina Praed</b> Pharmacist	Head of Prescribing and Medicines Optimisation NHS Kernow
<b>Kathryn Wisner</b> Pharmacist	Pharmaceutical Advisor NHS Kernow
<b>Mr M Wilcock</b> Pharmacist	Head of Prescribing Support Unit, RCHT NHS Kernow Clinical Lead
<b>Dr Jonathan Katz</b> GP	NHS Kernow Clinical Lead
<b>Dr Martin Ronchetti</b> GP	NHS Kernow Clinical Lead
<b>Lisa Johnson</b> Nurse	Nurse consultant, Infection Control NHS Kernow
<b>Dr. Prithwiraj Chakrabarti</b> Consultant Microbiologist	Consultant Microbiologist & Infection Control Doctor RCHT

**Patient Group Direction for the supply of Trimethoprim Tablets by Community Pharmacists in the management of Uncomplicated Urinary Tract Infections**

<b>Clinical Condition</b>	
Situation/condition	<ul style="list-style-type: none"> <li>• Treatment of uncomplicated urinary tract infections in women</li> </ul>
Inclusion criteria	<p>Women aged 18 years and over presenting with two or more of the following symptoms:</p> <ul style="list-style-type: none"> <li>• Dysuria</li> <li>• Urinary frequency</li> <li>• Nocturia</li> <li>• Urinary urgency</li> <li>• Suprapubic pain</li> </ul> <p>and urinalysis shows the presence of leucocytes, nitrites or blood. (see current protocol for urinalysis)</p>
Exclusion criteria	<ul style="list-style-type: none"> <li>• Previous treatment with any antimicrobial for UTI, including trimethoprim, in the last three months</li> <li>• Known allergy to Trimethoprim or any of its components</li> <li>• Women who refuse treatment/ no consent</li> <li>• All female patients under 18 years of age</li> <li>• Women presenting with symptoms of pyelonephritis i.e. fever, flank pain, chills, rigors, nausea, vomiting and headache</li> <li>• Women with associated vaginal discharge</li> <li>• Women who have had 2 or more urinary tract infections within the past 3 months or more than 5 during the previous 12 months</li> <li>• Pregnant or breastfeeding women</li> <li>• Diabetics</li> <li>• Renal disease</li> <li>• Blood dyscrasias</li> <li>• Women who have any urological abnormalities or had surgery involving the lower urinary tract</li> <li>• Women with an indwelling catheter</li> <li>• Any woman taking any of the following medicines; ciclosporin, bone marrow suppressants, digoxin, rifampicin, phenytoin, methotrexate, or if currently on a course of antibiotics</li> <li>• All men</li> </ul>
Action if patient excluded	<ul style="list-style-type: none"> <li>• Refer to GP for advice and treatment. If necessary provide the patient with a referral form giving extra information on condition</li> <li>• Advise on support for self-care where appropriate</li> </ul>
<b>Medicinal Product Information</b>	
Medicinal Product	<ul style="list-style-type: none"> <li>• Trimethoprim 200mg tablets</li> </ul>
Legal status	<ul style="list-style-type: none"> <li>• POM</li> </ul>
Dose and method of administration	<ul style="list-style-type: none"> <li>• One 200mg tablet by mouth every twelve hours for three days.</li> </ul>
Total number of doses	<ul style="list-style-type: none"> <li>• 6 doses/ tablets</li> </ul>
Special precautions	The World Health Organization (WHO) no longer advises that additional


**Patient Group Direction for the supply of Trimethoprim Tablets by Community Pharmacists in the management of Uncomplicated Urinary Tract Infections**

	<p>precautions are required when using combined hormonal contraception (CHC) with antibiotics that are not enzyme inducers.</p>
Follow up treatment	<ul style="list-style-type: none"> <li>• If unacceptable side effects occur discontinue taking the Trimethoprim immediately and seek medical advice.</li> </ul>
Advice that must be given	<ul style="list-style-type: none"> <li>• <b>If symptoms do not respond within 48 – 72 hours: Patient should make an appointment to see their GP and take an early morning midstream urine sample to this appointment.</b></li> <li>• Identify the patient information leaflet.</li> <li>• Take at regular intervals and complete the 3 day course even if original infection appears to be better.</li> <li>• Tablets should be swallowed whole with a glass of water.</li> <li>• Advise on personal hygiene.</li> <li>• Encourage patient to maintain a high fluid intake. (3 litres of clear fluids each day).</li> <li>• Mild side effects may be experienced. These may include stomach upset, nausea and vomiting, and mild headache. Seek medical advice if skin redness, skin rashes, or itching are a problem. (See current BNF for full list of side effects and warnings)</li> </ul>
Record keeping	<ul style="list-style-type: none"> <li>• Completion of PMR</li> <li>• Completion of PGD checklist</li> <li>• Completion of consent form and signature of patient for prescription charges/exemption</li> <li>• Completion of the audit claim</li> </ul>
Audit trail	<ul style="list-style-type: none"> <li>• PMR entry</li> <li>• The tablets must be labelled with the directions and <b>“Supplied under Patient Group Direction”</b>.</li> <li>• Two copies of checklist and consent form to be made; one to be retained in the pharmacy for 2 years. One to be sent to patient’s GP within 48 hours of supply for inclusion in the patient’s notes.</li> <li>• Electronic claims to be made in line with local arrangements</li> </ul>
Reporting procedure for adverse reactions	<ul style="list-style-type: none"> <li>• All severe reactions to Trimethoprim tablets 200mg supplied under this PGD are to be reported to the MHRA through the Yellow Card System</li> </ul>
References-general	<ul style="list-style-type: none"> <li>• <b>Current British National Formulary</b>, London: British Medical Association and Royal Pharmaceutical Society of Great Britain</li> <li>• <b>Current Joint Formulary</b></li> </ul>
Specific guidance	<ul style="list-style-type: none"> <li>• <a href="http://cks.nice.org.uk/urinary-tract-infection-lower-women#azTab">http://cks.nice.org.uk/urinary-tract-infection-lower-women#azTab</a></li> <li>• Current RCHT Management of Infection Guidance for Primary and Community Services (See Joint Formulary)</li> </ul>

**Patient Group Direction for the supply of Trimethoprim Tablets by Community Pharmacists in the management of Uncomplicated Urinary Tract Infections**

<b>Staff characteristics</b>	
Qualifications required	<ul style="list-style-type: none"> <li>Pharmacist currently registered with the General Pharmaceutical Council.</li> </ul>
Additional requirements	<ul style="list-style-type: none"> <li>Previous attendance at a specific NHS CIO/KCCG training event and satisfactory completion of any post-event training material <b>OR</b></li> <li>Satisfactory completion of the latest CPPE learning pack 'Responding to Minor Ailments' and learning assessment <b>AND</b></li> <li>Completion of self-assessment of competency form</li> <li>The Pharmacist must have returned the PGD signing-sheet with evidence of their accreditation and been subsequently authorised to provide the service by the NHS England Area Team/KCCG Prescribing Team in an accredited pharmacy</li> <li>Familiarity and adherence to RPSGB "Practice Guidance ; Diagnostic Testing and Screening Service" accessed at <a href="http://www.rpharms.com/support-pdfs/diagnostic-testing-screening-services.pdf">www.rpharms.com/support-pdfs/diagnostic-testing-screening-services.pdf</a></li> </ul>
Requirements for continuing training and education	<ul style="list-style-type: none"> <li>CPD in the management of urinary tract infections</li> <li>Annual self-assessment of competency</li> </ul>

<b>Management</b>	
Date of PGD	<ul style="list-style-type: none"> <li>1<sup>st</sup> April 2016</li> </ul>
Date this PGD becomes due for review	<ul style="list-style-type: none"> <li>31<sup>st</sup> March 2017</li> </ul>

<b>Approved by:</b>	<b>Name</b>	<b>Signature</b>
NHS Kernow CCG Head of Prescribing and Medicines Optimisation	Georgina Praed	
NHS Kernow CCG GP Prescribing Lead	Dr Nick Gibson	
NHS Kernow CCG Director of Clinical and Corporate Affairs	Natalie Jones	N/A

**Patient Group Direction for the supply of Trimethoprim Tablets by Community Pharmacists in the management of Uncomplicated Urinary Tract Infections**

**PRIVATE AND CONFIDENTIAL**

Patient Details:    Name Address
-------------------------------------

**Check List for Management of Uncomplicated Urinary tract Infections in Women**

Inclusion criteria	Yes	No
Patient is present at consultation and consents to treatment		
Patient is aged 18 years or over		
Patient presents with two or more of the following symptoms: dysuria, urinary frequency, nocturia, urinary urgency, suprapubic pain		
Urinalysis shows the presence of leucocytes, nitrites or blood.		
Criteria for exclusion for treatment checked and none apply.		
Consent form completed by Pharmacist & signed. Prescription charge collected if applicable and form signed by patient.		
PMR completed and Trimethoprim 200mg tablets labelled as per PGD.		
Treatment regimen understood including: <ul style="list-style-type: none"> <li>• <b>Advice given if symptoms do not respond within 48 – 72 hours : Patient should make an appointment to see their GP and take an early morning midstream urine sample to this appointment.</b></li> </ul>		
Follow up advice given on measures to reduce recurrent episodes, e.g. increase fluid intake.		

Pharmacist's Signature

Date

Exclusion criteria	Yes	No
Allergy to Trimethoprim or any component of the tablet		
<b>Previous treatment with any antimicrobial for UTI, including trimethoprim, in the last THREE MONTHS</b>		
Presenting with any of the following symptoms, fever, flank pain, chills, rigors, nausea, vomiting and headache.		
Presenting with vaginal discharge		
Already had 2 or more UTI's in past 3 months or more than 5 during the previous 12 months.		
Woman is pregnant or breastfeeding.		
Woman has diabetes, or blood dyscrasias		
Has renal disease, urological abnormalities or had surgery involving the lower urinary tract.		
On any of the following medicines: ciclosporin, bone marrow suppressants, digoxin, rifampicin, phenytoin, methotrexate		
Already taking a course of antibiotics.		

If the patient answers yes to any of the exclusion criteria then they must be referred to GP.



**Patient Group Directions for the treatment of Uncomplicated urinary Tract Infection under the NHS Kernow Minor Ailments Scheme**

**April 2016 Version 9  
Pharmacist Signing Sheet**

In order to continue supplying medication under PGDs to treat Uncomplicated UTI in women as part of the NHS Kernow Minor Ailments Scheme from **1<sup>st</sup> April 2016** all pharmacists must complete and return this signing sheet. The new PGDs and associated paperwork must then be used from **1<sup>st</sup> April 2016**.

<u>Declaration</u>		
<ul style="list-style-type: none"> <li>• <i>I have read and understood the April 2016 PGD for the treatment of Uncomplicated urinary Tract Infection in Women and I am happy to use this from the 1<sup>st</sup> April 2016</i></li> <li>• <i>I have achieved the required accreditation to operate these PGDs</i></li> <li>• <i>I will undertake a self-assessment of competency prior to using this PGD</i></li> <li>• <i>I will undertake an annual self-assessment of competency to inform my CPD</i></li> </ul>		
PGD title	Pharmacist name (PLEASE PRINT) and signature	Date
Trimethoprim tablets (Version 9)		

Evidence of Accreditation ( <b><u>MUST BE COMPLETED</u></b> )	Date	Tick
Date of attendance at a previous PCT/CCG Training Session <b>OR</b>		
Certificate of Completion of current CPPE 'Responding to Minor Ailments' pack		

**Contact Details (PLEASE PRINT)**

Regular Pharmacy/Other \_\_\_\_\_  
 Address and postcode \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Email \_\_\_\_\_

Please copy for your records and send this form with the CPPE certificate (if applicable) to:

**NHS Kernow Medicines Optimisation Team  
 Sedgemoor Centre,  
 Priory Road,  
 St Austell,  
 CORNWALL,  
 PL25 5AS**

